K083580

# 510(k) Application Summary

K083580 - Revision IV, Submission Date: December 19th, 2010 JUN 22 2009

1. **Submitter Information:** AEGIS Regulatory, Inc. - Robert T. Wagner
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Knoxville, TN 37922
Tel.: 865-982-5552
Email: bob@bobwagner.net

**For Manufacturer:** LED Intellectual Properties, LLC
Attn: Steve Marquese
9832 Chesterfield Circle
Santa Ana, CA 92705
Tel.: (949) 394-2427

2. **General Information**

2.1 Classification Name: ILY – Infrared Lamp, therapeutic heating (Dual Use)

2.2 Common/Usual Name: LIghtStim

2.3 Proprietary Names: Pain Therapy Light, Model 1301

2.4 Classification: Class II

2.5 Classification Number: 1.) 878.5500

3. **Description:**

Pain Therapy Light Model 1301 is a hand-held device consisting of low intensity light emitting diodes (LED's) that provide infra-red light to the skin. Physical components include an LED array emitting 630, 660, 855 and 940nm respectively in a handheld "wand" configuration containing a simple "in/out" integrated chip with external, manual on/off switch, a single electronic resistor, and a removable 9 volt AC-to-DC power supply. Treatment times are as required by the user, and specified by the User's Manuals for product code ILY indications.

4. **Intended Use:**

**LightStim Pain Relief Light (handheld wand)**
**Product Code – ILY**

**Indications for Use:** The Pain Therapy Light, model: PTL, is an Over-The-Counter hand held device intended to emit energy in the visible and near infrared spectrum to provide topical heating for the purpose of elevating

tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain or muscle spasm, the temporary increase in local and blood circulation, and the temporary relaxation of muscles.

**5. Substantial Equivalence to Predicate Device(s):**

**Pain Therapy Light:** This device is substantially equivalent to the following predicate devices, which are currently in safe and effective commerce:

1. Quantum Warp 10 Light Delivery System – K032229
2. Pain Relief Bio-Beam 660+940 & Med Light 1630+2630 – K042813
3. Terra Quant MQ2000 V.5 & handy Rx MQ2007 – K061614
4. Acubeam, Super Nova, Dio – K022888

**6. Performance Standards:**

These devices have been tested under and are in compliance with performance standards that have been established for such devices under Section 878 of the Federal Food, Drug, and Cosmetics Act. All electrical and radiological products made by the applicant have been OSHA/NRTL listed, and have received constituent marks.

**7. Labeling:**

As attached and in User's Manuals (Attached Version 2.0) – Numerous technical warnings and advisements to insure proper use and maintenance.

**8. Statement of Safety and Effectiveness:**

These products have been used safely and effectively in clinical testing applications within the United States, with no negative reports or claims submitted to FDA / CDRH, for over 7 years prior to the date of this submission.

**9. Over-The-Counter Variance Request:**

As identical predicates of this device have been in safe and effective applications by layperson users, Over-The-Counter Variance is requested.

**10. Design and Use of the Device(s):**

| | |
|---|---|
| Is the device intended for prescription use?..... | NO |
| Is the device intended for over-the-counter use?..... | YES |
| Are its components derived from a tissue or other biologic source?..... | NO |
| Is the device provided sterile?..... | NO |
| Is the device intended for single use?..... | NO |

| | |
|---|---|
| Is the device a reprocessed single use device? | NO |
| Does the device contain a drug? | NO |
| Does the device contain a biologic? | NO |
| Does the device use software? | NO |
| Does the submission include clinical information | NO |
| Is the device implanted? | NO |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 22 2009

LED Intellectual Properties, LLC
% AEGIS Regulatory, Inc.
Mr. Roberty Wagner
1131 Anthem View Lane
Knoxville, Tennessee 37922

Re: K083580
Trade/Device Name: LED Intellectual Properties, LLC – Pain Therapy Light model: PTL
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: June 5, 2009
Received: June 17, 2009

Dear Mr. Wagner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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## Indications for Use

510(k) Number: K083580

Device Name: LED Intellectual Properties, LLC - Pain Therapy Light model: PTL

Indications For Use:

The Pain Therapy Light, model: PTL, is an Over-The-Counter hand held device intended to emit energy in the visible and near infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain or muscle spasm, the temporary increase in local and blood circulation, and the temporary relaxation of muscles.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices



510(k) Number K